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Underwater irradiator means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

§ 36.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission, other than a written interpretation by the General Counsel, will be recognized to be binding upon the Commission.

§ 36.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0158.

(b) The approved information collection requirements contained in this part appear in §§ 36.11, 36.13, 36.17, 36.19, 36.21, 36.53, 36.69, 36.81, and 36.83.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

- (1) In § 36.11, NRC Form 313 is approved under control number 3150-0120.
- (2) [Reserved]

[58 FR 7728, Feb. 9, 1993, as amended at 62 FR 52187, Oct. 6, 1997]

10 CFR Ch. I (1-1-06 Edition)

Subpart B—Specific Licensing Requirements

§ 36.11 Application for a specific license.

A person, as defined in § 30.4 of this chapter, may file an application for a specific license authorizing the use of sealed sources in an irradiator on Form NRC 313, "Application for Material License." Each application for a license, other than a license exempted from part 170 of this chapter, must be accompanied by the fee prescribed in § 170.31 of this chapter. The application and one copy must be sent to the appropriate NRC Regional Office listed in appendix D to part 20 of this chapter.

§ 36.13 Specific licenses for irradiators.

The Commission will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

(a) The applicant shall satisfy the general requirements specified in § 30.33 of this chapter and the requirements contained in this part.

(b) The application must describe the training provided to irradiator operators including—

- (1) Classroom training;
- (2) On-the-job or simulator training;
- (3) Safety reviews;
- (4) Means employed by the applicant to test each operator's understanding of the Commission's regulations and licensing requirements and the irradiator operating and emergency procedures; and
- (5) Minimum training and experience of personnel who may provide training.

(c) The application must include an outline of the written operating and emergency procedures listed in § 36.53 that describes the radiation safety aspects of the procedures.

(d) The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify

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who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

(e) The application must include a description of the access control systems required by § 36.23, the radiation monitors required by § 36.29, the method of detecting leaking sources required by § 36.59 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(f) If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Commission. The description must include the—

(1) Instruments to be used;
(2) Methods of performing the analysis; and

(3) Pertinent experience of the individual who analyzes the samples.

(g) If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the Commission or an Agreement State to load or unload irradiator sources.

(h) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by § 36.61.

§ 36.15 Start of construction.

The applicant may not begin construction of a new irradiator prior to the submission to NRC of both an application for a license for the irradiator and the fee required by § 170.31. As used in this section, the term “construction” includes the construction of any portion of the permanent irradiator structure on the site but does not include: Engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and

other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Atomic Energy Act of 1954, as amended, and rules, regulations, and orders issued under the Act.

§ 36.17 Applications for exemptions.

(a) The Commission may, upon application of any interested person or upon its own initiative, grant any exemptions from the requirements in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(b) Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this part. The Commission will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

§ 36.19 Request for written statements.

(a) After the filing of the original application, the Commission may request further information necessary to enable the Commission to determine whether the application should be granted or denied.

(b) Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Commission's request, submit written statements to enable the Commission to determine whether the license should be modified, suspended, or revoked.

Subpart C—Design and Performance Requirements for Irradiators

§ 36.21 Performance criteria for sealed sources.

(a) *Requirements.* Sealed sources installed after July 1, 1993:

(1) Must have a certificate of registration issued under 10 CFR 32.210;